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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,345	07/06/2001	Ian Hector Frazer	10338-5 US (2423066/VPA)	4929

570 7590 10/02/2002

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2005 MARKET STREET  
PHILADELPHIA, PA 19103

EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 10/02/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/900,345

Applicant(s)

FRAZER ET AL.

Examiner

Terry Mckelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to method for determining the translational efficiency of an individual codon in a cell, classified in class 435, subclass 6.
- II. Claims 4-6, drawn to method for producing progenitor cell or organism comprising a synthetic construct, classified in class 435, subclass 455 and class 800, subclass 21+.
- III. Claims 7-10, drawn to synthetic construct, vector and cell comprising the synthetic construct, classified in class 435, subclasses 320.1, 325, 419, and 243, and class 536, subclass 23.1.
- IV. Claims 11-14, drawn to method of constructing a synthetic polynucleotide, classified in class 435, subclass 91.4.
- V. Claims 15-22, drawn to synthetic polynucleotide, vector and cell comprising synthetic polynucleotide, classified in class 536, subclass 23.1 and class 435, subclasses 243, 320.1, 419, and 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group III and Groups I-II are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process, as evidenced by the distinct inventions of Groups I-II. Also, the synthetic construct, etc, can be used in any of the many assay methods in the art that use reporter genes.

Inventions of Group IV and Group V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by a materially different process, replacement of codons according to codon usage in the particular cell.

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Inventions of Groups I-II and IV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I-II comprise steps which are not required for or present in the methods of the other groups. (Although Group II claims are indicated as further comprising the methods of Group I claims, the Group I claims are drawn to testing which is done separately from making the final progenitor cells and organisms. That is, the claimed invention of Group II are not methods for determining the translational efficiency of a codon, but instead a method for producing progenitor cells or organisms because the final steps are not the measurement steps like in the methods of Group I.) The end result of the methods are different: determination of the translational efficiency of an individual codon (Group I), production of a progenitor cell or organism comprising a synthetic construct (Group II), and constructed synthetic construct (Group IV). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group III and Group IV, and Group V and Groups I-II are biologically and functionally different and

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distinct from each other and thus one does not render the other obvious. The products of Groups III and V are not made or used in the methods of Group IV and Groups I-II, respectively. The operation, function and effects of the products of Groups III and V are completely different and distinct from the operation, function and effects of the methods of Groups IV and I-II. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The synthetic construct, vector, and cell of Group III and the synthetic polynucleotide, vector, and cell of Group V are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The products of one group are not needed to produce the products of the other group. Therefore, the inventions of the two groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for Group III is not co-extensive with the search for Group V, with regard to the non-patent literature search because the two products are comprised of different structures, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014.

NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

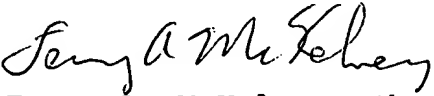
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Any inquiry concerning missing attachments or other minor formalities of this communication should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Terry A. McKelvey, Ph.D.  
Primary Examiner  
Art Unit 1636

October 1, 2002